Docket No: AM101017 Patent

Remarks/Arguments

Claims 1-15 are pending and have been rejected. In this Amendment: claims 1-6 and 13 have been amended; claims 7-12 and 14-15 have been canceled; and new claims 16-20 have been added.

The Examiner has rejected "Claims 13 and 16" (we assume that "Claims 13 and 15" is intended) under 35 U.S.C. § 112 as being indefinite because these claims are directed to a use without setting forth method/process steps. Applicants have amended claim 13 to put it in proper form, and have canceled claim 15. Currently amended claim 13 is not believed to be indefinite; therefore, withdrawal of this rejection is respectfully solicited.

Applicants thank the Examiner for noting that the terminal period was omitted from claim 10. This claim has been canceled, however, for other reasons.

Claims 1-15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lonnerdal et al. This reference has been cited as disclosing a soy formula for infants in which the phytate has been removed and the soy protein hydrolyzed, including having a soy content of 60 mg/L and a degree of soy protein hydrolysis of 6.3%. Applicants traverse this rejection for the reasons set forth below.

The currently claimed invention is a <u>method</u> comprising feeding a human infant an infant formula as specified in the claims. The Applicants do not claim the formula per se. Lonnerdal et al. describes the feeding of various types of nutritional formulae to rats and monkeys, mainly to compare the effects the different formulae have on zinc and copper absorption. This reference does not teach feeding a <u>human infant</u> a formula according to Applicants' claims.

Should the Examiner believe that it would be obvious to feed a formula according to Lonnerdal et al. to a human infant, Applicants wish to point out that Applicants' specification contains evidence that the claimed method unexpectedly leads to enhanced infant growth. For example, on page 12, lines 15-16, the specification states: "The mean weight change from baseline was higher for the infants fed the experimental formula at each point measured." And on page 12, lines 22-23, the specification states: "The infants in the experimental group were statistically significantly longer, on average, than the infants in the

Docket No: AM101017 Patent

control group...." In contrast, when Lonnerdal et al. measured growth in monkeys in "Monkey study 2", the results showed that: "There were no significant differences in weight or height between groups at any time." (reference page 492, column 2, last full paragraph) Of course, Lonnerdale et al. never fed human infants, leaving it to Applicants to make the surprising discovery that feeding human infants according to the claimed invention significantly enhances human infant growth. Therefore, the claimed method and its effects on human infants are not obvious from the teachings of the cited reference.

The cited art fails to teach feeding a human infant a formula according to the claimed invention, and fails to show knowledge of the growth enhancing effects that the claimed method would provide. One seeking a soy-based infant formula that would enhance the growth of human infants would not be motivated by this reference to practice Applicants' claimed method.

For the foregoing reasons, Applicants do not believe that the claimed method has been anticipated by the cited reference, and respectfully request withdrawal of the instant rejection under § 102(b).

Claims 1-15 have been rejected under 35 U.S.C. § 103(a) as bring unpatentable over Wong et al. (2001/0018197 A1). This reference has been cited as teaching a method of purifying soy protein by removing ribonucleic acids, phytic acid and phytates from protein material for use in infant formula. The Examiner has stated that the reference teaches a composition containing phytic acid within Applicants' claimed range, but does not teach the claimed degree of protein hydrolysis. The Examiner has stated that Lonnerdal et al. makes it obvious to apply the same degree of hydrolysis to the composition of Wong et al. Applicants traverse this rejection for the following reasons.

Wong et al. teaches a method for purifying vegetable protein materials, but does not teach an infant formula comprising the purified protein material. Wong et al. also does not teach a method of feeding an infant according to the claimed invention. The Examiner appears to be suggesting that it would have been obvious to one of ordinary skill in the art seeking a soy-based infant formula to: (1) select the material of Wong et al.; then (2) hydrolyze the material of Wong et al. to the degree of the material of Lonnerdal et al., and then (3) prepare an infant formula containing that material. Applicants cannot find in the prior art the motivation for doing so.

Docket No: AM101017

Patent

Furthermore, even if one were inspired to do what the Examiner suggests, it would not be obvious from the cited art that feeding such a formula to a human infant would significantly enhance the infant's growth, as has been surprisingly discovered by Applicants. The cited prior art fails to teach a method of feeding a human infant according to the claimed invention, and fails to teach the growth enhancing effects that the claimed method provides.

For all the foregoing reasons, Applicants believe that the claimed invention is patentable over Wong et al., and respectfully request the withdrawal of the rejection under §103(a).

Applicants solicit the allowance of claims 1-6, 13, and 16-20 and advancement of this case to issue at an early date. Please charge any fees due herewith to Dep. Acct. #01-1425.

Respectfully submitted,

Attorney for Applicants

Reg. No. 32,803

Wyeth Patent Law Department Five Giralda Farms Madison, NJ 07940 Tel. No. (973) 660-7657